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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.

First Inventor

Title

Express Mail Label No.

Francis X Smith

EF107952425

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
 2. ☒ Applicant claims small entity status.
See 37 CFR 1.27.
 3. ☒ Specification [Total Pages 16]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
 4. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets ☐
 5. Oath or Declaration [Total Pages ☐ - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63 (d))
(for continuation/divisional with Box 17 completed)
 - i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Form (CRF)
 - b. Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
 - c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☐ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Other:

17. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP)

of prior application No. _____

Prior application information:

Examiner _____

Group / Art Unit _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

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or ☐ Correspondence address below

Name

Chris Blank

Address

4 BICENTENNIAL SQ.

City

CONCORD

State

NH

Zip Code

03301

Country

USA

Telephone

603 227 5248

Fax

Name (Print/Type)

Chris Blank

Registration No. (Attorney/Agent)

31237

Signature

C Blank

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Jc932 U.S. PTO
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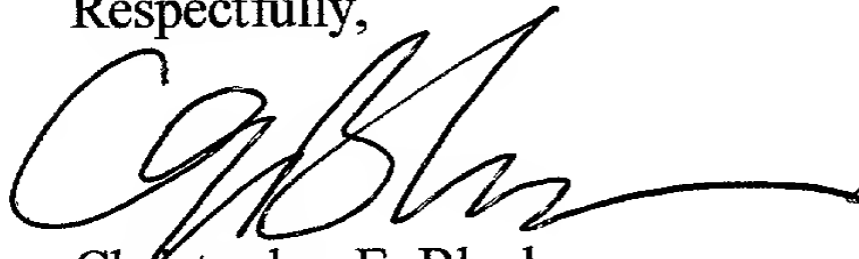
November 4, 2000

Small Entity Declaration and Certificate of Mailing

The following correspondence is being deposited with the United States mail, Express mail addressed to the above address. Applicants named in the attached applications qualify as small entities under the law to the best of my knowledge.

Express Mail No. EF 107995242 US

Respectfully,



Christopher E. Blank
Reg. No. 31,237
BGB Legal Services
4 Bicentennial Square
Suite 2b
Concord, New Hampshire 03301

Ph 603 227 5248
Fx 603 227 5263

0970633-10400

Improved Ophthalmic and Contact Lens Wetting Solutions

Inventors

Francis Xavier Smith

John Randall Tracy

0970630760

Background

The present invention relates to novel ophthalmic solutions that contain an ethoxylated glyceride as an additive to improve the wettability and to decrease the degree of protein and polymeric preservative binding to contact lens surfaces. These compositions may also comprise other agents in contact lens and ophthalmic solutions such as buffers, tonicity agents, wetting agents, enzymes, hydrogen peroxide, demulcents, thickeners, sequestering agents (chelating agents), surface active agents and preservative agents. The ethoxylated glycerides are particularly useful in contact lens treatment solutions, contact lens wetting solutions, solutions used to store contact lenses and solutions used to clean or rinse contact lenses. It has been found that surprisingly the addition of ethoxylated glycerides improve the comfort of lenses treated with such solution and that this increased comfort is surprisingly long-lasting in its effect. The ethoxylated glycerides may be mono-, di- or triglycerides and include

The solutions of the present invention are made by one of two methods. First the ethoxylated glyceride may be melted and added to an aqueous solution which includes the other agents to be used in the desired formulation, or the additional agents may be added prior to the addition of the melted ethoxylated glyceride. Second, the ethoxylated glyceride may be dissolved in an alcohol base and this liquid mixture, added to the aqueous base. Ethoxylated glycerides are commercially available from numerous commercial sources and include Polyoxyl 40 hydrogenated castor oil (Cremophor RH 40), polyoxyl 60 hydrogenated castor oil (Cremophor RH 60), PEG-30 Castor Oil (Incrocas 30), PEG-35 Castor Oil (Cremophor EL, Incrocas 35), or PEG-40 Castor Oil (Cremophor EL, Incrocas), Cremophor EL®, Emulphor EL®, glycerol polyethyleneglycol riciinoleate, glycerol polyethyleneglycol oxystearate, polyethoxylated hydrogenated castor oil, or polyethoxylated vegetable oil. The ethoxylated glycerides useful in the present invention may include surfactants sold as PEG-6 Caprylic/Capric Glycerides PEG-8 Caprylic/Capric Glycerides; PEG-2 Castor Oil; PEG-3 Castor Oil; PEG-4 Castor Oil; PEG-5 Castor Oil; PEG-8 Castor Oil; PEG-9 Castor Oil; PEG-10 Castor Oil; PEG-11 Castor Oil; PEG-15 Castor Oil; PEG-20 Castor Oil; PEG-25 Castor Oil; PEG-30 Castor Oil; PEG-33 Castor Oil; PEG-35 Castor Oil; PEG-36 Castor Oil; PEG-40 Castor Oil; PEG-50 Castor Oil; PEG-54 Castor Oil; PEG-55 Castor Oil; PEG-60 Castor Oil; PEG-100 Castor Oil; PEG-200 Castor Oil; PEG-18 Castor Oil Dioleate; PEG-60 Corn Glycerides; PEG-20 Evening Primrose Glycerides;

PEG-60 Evening Primrose Glycerides; PEG-7 Glyceryl Cocoate; PEG-30 Glyceryl Cocoate; PEG-78 Glyceryl Cocoate; PEG-80 Glyceryl Cocoate; PEG-12 Glyceryl Dioleate; PEG-15 Glyceryl Isostearate; PEG-20 Glyceryl Isostearate; PEG-30 Glyceryl Isostearate; PEG-60 Glyceryl Isostearate; PEG-12 Glyceryl Laurate; PEG-20 Glyceryl Laurate; PEG-23 Glyceryl Laurate; PEG-30 Glyceryl Laurate; PEG-10 Glyceryl Oleate; PEG-15 Glyceryl Oleate; PEG-30 Glyceryl Oleate; PEG-20 Glyceryl Ricinoleate; PEG-5 Glyceryl Sesquioleate; PEG-5 Glyceryl Stearate; PEG-10 Glyceryl Stearate; PEG-25 Glyceryl Stearate; PEG-30 Glyceryl Stearate; PEG-120 Glyceryl Stearate; PEG-200 Glyceryl Stearate; PEG-28 Glyceryl Tallowate; PEG-80 Glyceryl Tallowate; PEG-200 Glyceryl Tallowate; PEG-5 Glyceryl Triisostearate; PEG-5 Hydrogenated Castor Oil; PEG-7 Hydrogenated Castor Oil; PEG-16 Hydrogenated Castor Oil; PEG-20 Hydrogenated Castor Oil; PEG-25 Hydrogenate Castor Oil; PEG-30 Hydrogenate Castor Oil; PEG-35 Hydrogenate Castor Oil; PEG-40 Hydrogenate Castor Oil; PEG-45 Hydrogenate Castor Oil; PEG-50 Hydrogenate Castor Oil; PEG-54 Hydrogenate Castor Oil; PEG-55 Hydrogenate Castor Oil; PEG-60 Hydrogenate Castor Oil; PEG-80 Hydrogenate Castor Oil; PEG-100 Hydrogenate Castor Oil; PEG-200 Hydrogenate Castor Oil; PEG-40 Hydrogenated Castor Oil PCA Isostearate; PEG-5 Hydrogenated Corn Glycerides; and PEG-8 Hydrogenated Fish Glycerides; which are all available from known commercial sources

The solutions of the present invention may contain other additives including but not limited to buffers, tonicity agents, demulcents, wetting agents, preservatives, sequestering agents (chelating agents), surface active agents, and enzymes.

Other aspects of the claimed solutions include adding to the solution from 0.001 to 1 weight percent chelating agent (preferably disodium EDTA) and/or additional microbicide, (preferably 0.00001 to 0.1 or 0.0000 1 to 0.01) weight percent polyhexamethylene biquanide (PHMB0, N-alkyl-2-pyrrolidone, chlorhexidine, polyquaternium- 1, hexetidine, bronopol, alexidine, low concentrations of hydrogen peroxide, and ophthalmologically acceptable salts thereof

Ophthalmologically acceptable chelating agents useful in the present invention include amino carboxylic acid compounds or water-soluble salts thereof, including ethylenediaminetetraacetic acid, nitrilotriacetic acid, diethylenetriamine pentaacetic acid,

hydroxyethylethylenediaminetriacetic acid, 1,2-diaminocyclohexanetetraacetic acid, ethylene glycol bis (beta-aminoethyl ether) in N, N, N', N' tetraacetic acid (EGTA), aminodiacetic acid and hydroxyethylamino diacetic acid. These acids can be used in the form of their water soluble salts, particularly their alkali metal salts. Especially preferred chelating agents are the di-, tri- and tetra-sodium salts of ethylenediaminetetraacetic acid (EDTA), most preferably disodium EDTA (Disodium Edetate).

Other chelating agents such as citrates and polyphosphates can also be used in the present invention. The citrates which can be used in the present invention include citric acid and its mono-, di-, and tri-alkaline metal salts. The polyphosphates which can be used include pyrophosphates, triphosphates, tetrphosphates, trimetaphosphates, tetrametaphosphates, as well as more highly condensed phosphates in the form of the neutral or acidic alkali metal salts such as the sodium and potassium salts as well as the ammonium salt.

The pH of the solutions should be adjusted to be compatible with the eye and the contact lens, such as between 6.0 to 8.0, preferably between 6.8 to 7.8 or between 7.0 to 7.6. Significant deviations from neutral (pH 7.3) will cause changes in the physical parameters (i.e. diameter) in some contact lenses. Low pH (pH less than 5.5) can cause burning and stinging of the eyes, while very low or very high pH (less than 3.0 or greater than 10) can cause ocular damage.

The additional preservatives employed in the present invention are known, such as polyhexamethylene biguanide, N-alkyl-2-pyrrolidone, chlorhexidine, polyhexamethylenbiguanide, alexidine, polyquaternium- 1, hexetidine, bronopol and a very low concentration of hydrogen peroxide, e.g., 30 to 200 ppm.

The solutions of the invention are compatible with both rigid gas permeable and hydrophilic contact lenses during storage, cleaning, wetting, soaking, rinsing and disinfection.

A typical aqueous solution of the present invention may contain additional ingredients which would not affect the basic and novel characteristics of the active ingredients described earlier, such as tonicity agents, surfactants and viscosity inducing agents, which may aid in either the

lens cleaning or in providing lubrication to the eye. Suitable tonicity agents include sodium chloride, potassium chloride, glycerol or mixtures thereof The tonicity of the solution is typically adjusted to approximately 240-310 milliosmoles per kilogram solution (mOsm/kg) to render the solution compatible with ocular tissue and with hydrophilic contact lenses. In one embodiment, the solution contains 0.01 to 0.5 weight percent sodium chloride.

Suitable viscosity inducing agents can include lecithin or the cellulose derivatives such as hydroxymethylcellulose, hydroxypropylcellulose and methylcellulose in amounts similar to those for surfactants, above.

EXAMPLE 1

Hydrophilic contact lenses were placed flat onto glass slides and rinsed with water to remove any debris. These slides were placed in a petri dish and covered with a few drops of each of the test solutions previously prepared in either water, an aqueous isotonic sodium chloride solution, or an aqueous phosphate buffered solution made isotonic with sodium chloride and adjusted to pH 7.3. Each *petri* plate was covered and placed in a refrigerator overnight. The following day, the slides were removed and allowed to equilibrate to room temperature. The lenses were rinsed with water and the excess water was removed. One 5 uL drop of mineral oil stained with Oil Red O was placed onto one lens for each solution. After ten minutes, the lenses were observed for the ability of the oil drop to spread.

Additive	Solution Matrix	Oil Dispersibility	Water Dispersibility
1% polyoxyl 40 hydrogenated castor oil (Cremophor RH 40)	water	4	5
1% polyoxyl 40 hydrogenated castor oil (Cremophor RH 40)	buffer water	5	5
1% polyoxyl 40	sodium choride	2	5

hydrogenated castor oil (Cremophor RH 40)	water		
1% polyoxyl 40 hydrogenated castor oil (Cremophor RH 40)	buffer sodium chloride water	3	5
1% Polysorbate 80 (Tween 80)	sodium choride water	4	5
1% Poloxamine 1107 (Tetronic 1107)	sodium choride water	2	5
1% Poloxamer 407 (Pluronic F127)	sodium choride water	2	5
1% Polysorbate 80 (Tween 80)	buffer sodium chloride water	3	5
1% Poloxamine 1107 (Tetronic 1107)	buffer sodium chloride water	1	5
1% Poloxamer 407 (Pluronic F127)	buffer sodium chloride water	1	5
Water	water	1	5

- Key
- 1 non-spreading drop
 - 2 poor spreading drop
 - 3 moderate spreading drop
 - 4 increased spreading drop
 - 5 thin spreading film

The results demonstrates that exposure of the contact lens to the ethoxylated glyceride will generate a durable modified surface capable of allow the formation of a thin oil and aqueous film. This characteristic mimics mucin and is essential for the proper tear layer formation of

over the lens. A score of 3 or better is considered acceptable. This experiment also illustrates the synergistic improvement when the ethoxylated glyceride is exposed in the presence of a buffer. The inability of the Poloxamer and Poloxamine to allow the oil film to spread across the lens demonstrates that not all surface active agents will promote the spreading of a properly formed tear film over the contact lens surface.

EXAMPLE 2

Example of Protein Deposition Inhibition

Contact lenses were soaked and heated in test solutions to which a radio-labeled lysozyme was present in a known amount for a period of 12 hours at 37 degrees Celsius. The lenses were rinsed with distilled water in order to remove residual solution. The lenses were then assayed for protein deposition using a Beckman BioGamma 1 counter. Results were reported in ug/lens.

	Lens A ug/lens	Lens B ug/lens	Average ug/lens
Phosphate buffer control	1,043	865	954
Cremophor RH40 (1%) In Phosphate Buffer	15	23	19

Ethoxylated Castor Oil was a 1 percent w/v solution. The matrix control was phosphate buffer and sodium chloride. The polyoxyl 40 hydrogenated castor oil solution had lower protein binding than the control.

EXAMPLE 3

Example of Protein Deposition Inhibition

Isotonic aqueous phosphate buffered solutions were prepared and adjusted to pH 7.4. Contact lenses were soaked in 25 mL of the test solutions overnight. Afterwards, lysozyme was added to the tubes and warmed to 37 degrees Celsius for 12 hours. The lenses were rinsed with distilled water in order to remove residual solution. The lenses were assayed for protein deposition by the BCA method and detected on an HP PDA Spectrophotometer. Results were reported in ug/lens.

Example 6

The following are useful disinfecting solutions within the scope of the present invention that may be used for all purpose disinfecting solutions. They are made according to generally acceptable procedures except that the ethoxylated glycerides must be first be dissolved in warm water prior to the addition of the other components.

Constituent	Supplier	% Weight/ Volume	Amount
Purified water		to 80%	40 mL
Tricine	Spectrum	1.0%	0.500 g
Carnitine	Spectrum	0.25%	0.125 g
Betaine HCl	Spectrum	0.1%	0.050 g
Choline Chloride	Amresco	0.5%	0.250 g
Inositol	Spectrum	0.1%	0.050 g
Edetate Disodium	Spectrum	0.055%	0.0275 g
Polyoxyl 40 Hydrogenated Castor Oil	Cremophor RH 40 from BASF Co.	0.1%	0.5 mL of 10%
Hydrochloride Acid, 1N		as required for pH adjustment to 7.3	as required for pH adjustment to 7.3
Sodium Hydroxide, 1N		as required for pH adjustment to 7.3	as required for pH adjustment to 7.3
Purified Water		to 98%	Dilute to 49 mL
Sodium Chloride	Fisher	As required for tonicity adjustment 300 mOsm	As required for tonicity adjustment 300 mOsm
Polyhexamethylene- biguanide HCl	20% w/w solution available under the mark Cosmocil CQ from Avecia	0.0001%	50 uL of 0.1%
Purified Water		Balance to 100%	Dilute to 50 mL

Example 7

The following are formulations within the scope of the invention of formulations intended to be used as lens-vial solutions that are used to store lenses prior to their use. These solutions have the effect of treating the contact lens in the solution and rendering the lens more comfortable in use.

Constituent	Supplier	% Weight/ Volume	Amount
Purified water		to 80%	40 mL
Tricine	Spectrum	1.0%	0.500 g
Carnitine	Spectrum	0.25%	0.125 g
Inositol	Spectrum	0.1%	0.050 g
Hydrochloride Acid, 1N		as required for pH adjustment to 7.3	as required for pH adjustment to 7.3
Sodium Hydroxide, 1N		as required for pH adjustment to 7.3	as required for pH adjustment to 7.3
Polyoxyl 40 Hydrogenated Castor Oil	Cremophor RH 40 from BASF Co.	0.1%	0.5 mL of 10%
Purified Water		to 98%	Dilute to 49 mL
Sodium Chloride	Fisher	As required for tonicity adjustment 300 mOsm	As required for tonicity adjustment 300 mOsm
Purified Water		to 100%	Dilute to 50 mL

What is claimed is:

1. An ophthalmic contact lens solution comprising:
0.001 to 10 percent by weight ethoxylated glyceride;
0.001 to 2 weight percent of a physiologically acceptable buffer adjusted so the pH of solution is between 6.5 and 7.8 and the balance water.
2. An ophthalmic contact lens solution comprising:
0.001 to 10 percent by weight ethoxylated glyceride;
0.001 to 2 weight percent of a physiologically acceptable tonicity agent adjusted so the solution is isotonic between 200 and 400 mOsm
3. An ophthalmic solution comprising;
0.001 to 10 percent by weight ethoxylated glyceride;
0.00001 to 0.1 weight percent of a preservative agent.
4. The solution of claim 1 which further comprises 0.01 to 2 weight percent of a physiologically acceptable tonicity agent adjusted so the solution is isotonic between 200 and 400 mOsm
5. The solution of claim 4 that further comprises 0.00001 to 0.1 weight percent of a preservative.
6. The solution of claim 1 wherein the ethoxylated glyceride is chosen from the group of compounds consisting of Polyoxyl 40 hydrogenated castor oil (Cremophor RH 40), polyoxyl 60 hydrogenated castor oil (Cremophor RH 60), PEG-30 Castor Oil (Incrocas 30), PEG-35 Castor Oil (Cremophor EL, Incrocas 35), or PEG-40 Castor Oil (Cremophor EL, Incrocas), Cremophor EL®, Emulphor EL®, glycerol polyethyleneglycol ricinoleate, glycerol polyethyleneglycol oxystearate, polyethoxylated hydrogenated castor oil, or polyethoxylated vegetable oil.

7. The solution of claim 1 wherein the buffer is selected from the group consisting of organic amines, organic carboxylic acids, amphoterics, phosphates, or borates.
8. Method for rendering a contact lens wettable by contacting the surface of said lens with an aqueous solution comprising from .001 to about 10 percent by weight of an ethoxylated glyceride.
9. The method of claim 8 wherein the the ethoxylated glyceride is polyoxyl 40 hydrogenated castor oil.
10. The method of claim 7 wherein said ethoxylated glyceride is polyoxyl 60 hydrogenated castor oil.
11. The method of claim 7 wherein said ethoxylated glyceride is polyoxyl 40 hydrogenated castor oil.
12. The method of claim 7 wherein said ethoxylated glyceride is polyoxyl 35 castor oil.
13. The method of claim 7 wherein the aqueous solution further comprises the buffer bis(2-hydroxyethyl)iminotris(hydroxymethyl)methane (Bis-Tris) and its salts.
14. The method of claim 7 wherein the aqueous solution further comprises the 1,2-bis[tris(hydroxymethyl)-methylamino]propane (Bis-Tris Propane) and its salts.
15. The method of claim 7 wherein the aqueous solution further comprises the N-tris(hydroxymethyl) methyl glycine (Tricine) and its salts.
16. The method of claim 7 wherein the aqueous solution further comprises the N,N-bis(2-hydroxyethyl)-glycine (Bicine) and its salts.
17. The method of claim 7 wherein the aqueous solution further comprises the betaine and its salts.
18. The method of claim 7 wherein the aqueous solution further comprises the buffer phosphate and its salts
19. The method of claim 7 wherein the aqueous solution further comprises the buffer is borate and its salts
20. The method of claim 7 wherein the aqueous solution further comprises the is citrate and

its salts

21. The method of claim 7 wherein the aqueous solution further comprises is TRIS and its salts
22. The method of claim 7 wherein the aqueous solution further comprises the buffer is 2-amino-2-methyl-1,3-propanediol and its salts
23. The method of claim 7 wherein the aqueous solution further comprises the buffer is triisopropanolamine and its salts
24. The method of claim 7 wherein the aqueous solution further comprises the buffer is carnitine and its salts
25. The method of claim 7 wherein the aqueous solution further comprises the buffer is dimethyl glutamate and its salts
26. The method of claim 7 wherein the aqueous solution further comprises the buffer is creatine and its salts
27. The method of claim 7 wherein the aqueous solution further comprises the buffer is diethanolamine and its salts
28. The method of claim 7 wherein the aqueous solution further comprises the buffer is diisopropylamine and its salts
29. The method of claim 7 wherein the aqueous solution further comprises the buffer is triethanolamine and its salts
30. The method of claim 7 wherein the aqueous solution further comprises the buffer is triethylamine and its salts
31. The method of claim 7 wherein the aqueous solution further comprises the buffer is dimethyl aspartic acid and its salts
32. The method of claim 7 wherein the aqueous solution further comprises the buffer is imidazole and its salts
33. The method of claim 7 wherein the aqueous solution further comprises the buffer is histidine and its salts
34. The method of claim 7 wherein the aqueous solution further comprises the buffer is methyl aspartate and its salts
35. The method of claim 7 wherein the aqueous solution further comprises the buffer is Tris(hydroxymethyl)aminomethane (Tromethamine, TRIS) and its salts

35. A contact lens product comprising:

A contact lens;

A sealable container; and

An effective amount of an ophthalmic lens solution comprising:

0.001 to 10 percent by weight ethoxylated glyceride;

0.01 to 2 weight percent of a physiologically acceptable buffer adjusted

so the pH of solution is between 6.5 and 7.8 and the balance water.

37. The method of claim 7 wherein the buffer is glycine and its salts

38. The method of claim 7 wherein the buffer is lysine and its salts

39. The method of claim 7 wherein the buffer is histidine and its salts.,

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input type="checkbox"/> Declaration Submitted with Initial Filing OR <input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	Attorney Docket Number	
	First Named Inventor	FRANCIS SMITH
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	Examiner Name	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Improved ophthalmic and contact lens wetting solutions

(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY)

as United States Application Number or PCT International

Application Number

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(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
60/163,455	11-4-99	

[Page 1 of 2]

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Name

Chris Blank

Address

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SUITE 2B

City

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Country

USA

Telephone

603 227 5248

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NAME OF SOLE OR FIRST INVENTOR:

☐

A petition has been filed for this unsigned inventor

Given Name

(first and middle [if any])

FRANCIS X

Family Name
or Surname

SMITH

Inventor's
Signature

Francis X Smith

Date

11-3-00

Residence: City

Salem

State

NH

Country

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Citizenship

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NAME OF SECOND INVENTOR:

☐

A petition has been filed for this unsigned inventor

Given Name

(first and middle [if any])

John Randall

Family Name
or Surname

Tracy

Inventor's
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

Mailing Address

City

State

ZIP

Country

☐ Additional inventors are being named on the ____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.